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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/475,721   | 12/30/1999  | MATTHEW S. REIMINK   | 1610.IUS01          | 6766             |
| 22865  | 7590        | 09/15/2004           | EXAMINER            |                  |
| ALTERA LAW GROUP, LLC<br>6500 CITY WEST PARKWAY<br>SUITE 100<br>MINNEAPOLIS, MN 55344-7704 |             |                      | HON, SOW FUN        |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1772                 |                     |                  |

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                         |                  |
|------------------------------|-------------------------|------------------|
| <b>Office Action Summary</b> | Application No.         | Applicant(s)     |
|                              | 09/475,721              | REIMINK ET AL.   |
|                              | Examiner<br>Sow-Fun Hon | Art Unit<br>1772 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 July 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5-20,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-20,31-21 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Rejections Repeated*

1. The 35 U.S.C. 102(b) and 103(a) rejections are repeated for the same reasons of record in the Office action dated 07/28/03.

### *Response to Arguments*

2. Applicant's arguments filed 07/01/04 have been fully considered but they are not persuasive.

3. Applicant argues that in the present application, the polymer itself, and not the substrate, provides the form of the device, while in the device of Pietsch, the substrate provides the form of the device.

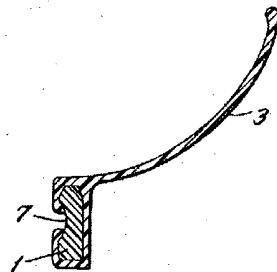


FIG.3

Applicant is respectfully directed to Fig. 3 above, in which Pietsch shows a cross-sectional view of the heart valve whereby the cusp material 3 encloses the support ring 1, and the boundary edge of the cusp has a rounded lobate thickened outline (column 8, lines 20-30). It can be seen that the cusp 3 provides the form of the device. The cusp 3 is made of flexible three-dimensionally crosslinked polymer (column 4, lines 20-30). The support ring 1 is made out of inorganic material (stainless steel, ceramics) (column 10, lines 10-15). Thus it can be seen that

the polymer (cusp material) itself, and not the inorganic substrate, provides the form of the device.

4. Applicant argues that Pietsch must be considered for its antithetical teachings, that Pietsch teaches that the support ring preferably consists of plastic material, and therefore teaches away from providing a support ring made of an inorganic material.

Applicant is respectfully apprised that Pietsch does teach that the support ring may be made out of inorganic material such as stainless steel, titanium, and ceramics, as well as thermoplastics (column 3, lines 45-55). Therefore Pietsch does not teach away from a support ring made of inorganic material.

5. Applicant argues that Applicant cannot find the teaching of crosslinked silicone rubber (polydimethylsiloxane) has high fatigue strength in alternate bending, high breaking strength of at least 8 N/mm<sup>2</sup> at a low Shore A hardness of 25-35, and an elongation at break of more than 400 % (column 4, lines 60-65), and requests supporting references.

Applicant may be referring to the term “silicone rubber”. Alger (Polymer Science Dictionary, 2<sup>nd</sup> Edition) teaches that “silicone rubber” is an alternate name for “silicone elastomer” (column 522a), the basic polymer being polydimethylsiloxane (column 521a).

6. Applicant’s arguments with respect to the combination of Pietsch with Sumimoto, and with MacGregor, directed against the valid use of Pietsch, have been addressed above.

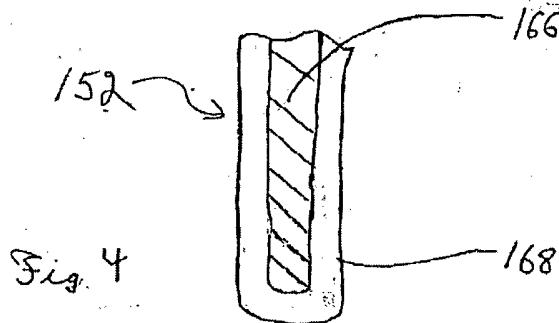
7. Applicant argues that the composite of MacGregor is formed into the shape of the device, while the polymer alone provides the shape of the device of Applicant.

Applicant is respectfully reminded that MacGregor is the secondary reference being used to compensate for the failure of the primary reference Pietsch to teach that the polymer is rigid.

8. Applicant's argument that the device set forth in claim 1: "a medical device comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the substrate", is different from Pietsch, has been addressed in paragraph 3 above. Furthermore, the polymer forms the structure of cusp which is substantially different from the structure of the inorganic support ring, thus providing the form of the device.

9. Applicant argument s that the device set forth in claim 10: "A medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate, wherein the flexible composite component can be bent at least about 100 degrees without extending the flexible composite component beyond its elastic limit", is different from Pietsch, has been addressed in paragraph 5 above. Furthermore, crosslinked polyether-urethanes are also taught by Pietsch to be suitable with a low Shore A hardness and a high breaking strength (column 4, lines 20-55).

10. In order to further prosecution, Applicant is respectfully reminded that the limitation "composite comprising an inorganic substrate and a polymer member" is broadly interpreted to comprise Pietsch. It is possible to rewrite claim 10, with support from the specification, based on original Figure 4 of Applicant, as "a medical device comprising an inorganic substrate and a polymer member covering at least a portion of the substrate, wherein the flexible composite component can be bent, through a cross-section of both polymer and inorganic substrate, at least about 100 degrees without extending the flexible composite component beyond its elastic limit" in order to distinguish the claims from Pietsch, as intended by Applicant.



Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon.  
Sow-Fun Hon

09/13/07

Harold Pyon  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  
1992

9/14/04